Contents: Internal Controlled Documents

Effective Date: **May 2002**

Point of Contact: Quality Program Office

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2. Revising Existing Controlled Documents	• Revise existing controlled documents applying one of the following subprocesses:
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	  ○ Proposed Revisions for Normal Change
	  ○ Proposed Revisions for Work- in-progress Change

3. Distributing Controlled Documents	• Distribute controlled documents applying one of the following subprocesses:
	  ○ Using a Controlled Distribution List
	  ○ Using Other Methods of Distribution

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Definitions	

Exhibits

Flowchart of Document Control

Guidelines for Developing Procedures

Forms

Document Review Tracking Sheet

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Training Requirements and Reporting Obligations

This subject area does not contain training requirements.

This subject area does not contain reporting obligations.

References

Calibration Subject Area

Engineering Design Subject Area

Integrated Safety Management System Program Description

Nonconformance and Corrective and Preventive Action Subject Area

Records Management Subject Area

Training and Qualifications Subject Area

Work Planning and Control for Experiments and Operations Subject Area

Standards of Performance

Management systems, standards, implementing procedures, and guidelines shall be developed with appropriate input from staff enabling them to effectively work in compliance with applicable requirements.

Facility configurations, operating envelopes, and the design basis shall be documented and controlled.

Managers shall develop, maintain, communicate, and manage appropriate plans, i.e., project plans, program plans, operations plans, and business plans.

Management System

This subject area belongs to the **Quality Management** management system.

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Introduction: Internal Controlled Documents

Effective Date: **May 2002**

Point of Contact: Quality Representative

This subject area applies to documents such as plans, manuals, procedures, and instructions that are internal to one or more divisions, departments, or projects, but are not Laboratory-wide. The documents may prescribe design and manufacturing operations and processes; inspection and test procedures; installation, construction, operating and maintenance procedures; monitoring procedures, research procedures, and protocols. Controlled documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to specific staff or used at the locations where the prescribed activity is performed.

This subject area **does not** cover internal procedures that are not controlled, classified documents, or research reports. Such documents are prepared, revised, and distributed according to guidelines developed by the originating organization. The following items are also not covered:

- Documents that are prepared by external parties (e.g., equipment operating/maintenance manuals). These external documents can be controlled, when appropriate, by cognizant staff.
- A posting or sign that is temporarily or permanently affixed as a warning, or to provide information/safety instructions to staff who may be exposed to hazards. These are covered by other requirements or SBMS documents (e.g., Safety Signs for Static Magnetic Fields exhibit in the Static Magnetic Fields Subject Area).

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Subject Area: ***Internal Controlled Documents***

1. Developing New Controlled Documents

Effective Date: **May 2002**

Point of Contact: Quality Representative

Applicability

This information applies to staff who develop new controlled documents, such as plans, manuals, procedures, work instructions, and operator aids.

Required Procedure

The staff member responsible for preparing new documents performs the following steps.

Step 1	The cognizant manager or designee determines if a controlled document is necessary, based on criteria, such as the following: • technical or operating processes are required to be documented (e.g., by a client, regulation, or contract) • identified hazards warrant a controlled document • an activity involves the operation, maintenance (corrective or preventive), test, or inspection of any safety-related system, structure, or component • documents are needed to ensure quality (e.g., data or standards traceability, reproducibility, or consistency of the process or data) • an off-normal or emergency operating condition might occur. **Note:** If the cognizant manager or designee determines that a controlled document is not warranted, no further action is necessary.
Step 2	The cognizant manager or designee assigns an author to develop the controlled document and provides guidance as necessary. When an internal procedure is being developed to implement a Laboratory-wide procedure (i.e., a subject area), the internal procedure must also comply with the requirements of the Laboratory-wide procedure. See the Guidelines for Developing Procedures exhibit, or the Calibration Subject Area. **Note:** For further information, contact your Quality Representative.

Step 3	The author develops the controlled document, which must contain the following elements, at a minimum: • document title • effective date • revision (e.g., Rev. 0, Rev. 1, Rev. A, or Rev. B) • approval(s). **Note:** Operator aids only need to be signed and dated, if the cognizant manager deems necessary, depending on the risk, importance, and critical nature of the equipment or operation. (See the Guidelines section below.) For internal procedures, manuals, and plans, the following additional elements are required: • applicability (e.g., staff or location) • work instructions • the method for documenting data or results to show compliance with a regulatory requirement (see the Guidelines for Developing Procedures exhibit). **Note:** Subject Matter Experts (e.g., Environment, Safety, and Health, and Quality Management experts) can help develop documents. **Note:** The core functions and guiding principles of the Integrated Safety Management System Program Description should be considered during the development of all documents. **Note:** Other elements may be needed to meet specific client requirements or expectations (such as data traceability, reproducibility, or documentation and associated procedural controls). See the Guidelines for Developing Procedures exhibit for more information. Also, the originating organization for the controlled document may require specific elements to be included.
Step 4	The cognizant manager or designee reviews and approves the document. Where appropriate, the cognizant manager or designee ensures that the core functions and guiding principles of Integrated Safety Management (ISM) are addressed. A hazards analysis is conducted in accordance with the screening criteria of Work Planning and Control for Experiments and Operations Subject Area, and appropriate controls are incorporated into the document. **Note:** The cognizant manager or designee may identify other reviewers depending on the document and the department/division's project-specific process for document control. Those reviews can be done in parallel or consecutively.
Step 5	The cognizant manager or designee determines if the document is to be incorporated into an existing BNL program such as the Environmental Management System (EMS) or Conduct of Operations. The document is reviewed periodically as per the program requirements. **Note:** For other types of documents, see the Guidelines section below for recommended review frequencies.
Step 6	The cognizant manager or designee completes the steps outlined in the section Distributing Controlled Documents.

Guidelines

If your organization does not have a consistent, approved process or format for developing technical or operating procedures, the use of the Guidelines for Developing Procedures exhibit is recommended.

When several individuals are reviewing the document, some method of tracking should be used. The Document Review Tracking Sheet provides a suggested form.

If the manager, designee, or one or more reviewers do not agree with the document, they can discuss their concerns with the author and attempt to resolve the differences. If the differences cannot be resolved, they should be taken to successively higher levels of management until they are resolved.

Consideration should be given to training personnel in new procedures, to assure users are trained and qualified to perform their assigned tasks and job functions. Additional details regarding training can be found in the Training and Qualifications Subject Area.

For an operator aid:

The following suggestions may be appropriate depending on the risk, importance, and critical nature of the equipment or operation. The cognizant staff should determine if these suggested practices are applicable.

- The operator aid should, when possible, be protected (e.g., laminated) and should be securely fastened to the equipment to which it refers.
- Operator aids may supplement approved procedures, but they should not be used in lieu of them.
- A listing of all approved operator aids should be maintained along with a copy of each aid posted in the facility. This list should be used during periodic reviews of operator aids to determine that they are still correct and necessary, and to provide a reference copy should an operator aid be missing during the review.
- It is important to ensure that these types of postings reflect the most current information available and that they do not supersede or conflict with any other controlled procedure or information.
- Operator aids should not obstruct an indicating device, nor should they impair a switch, button, or other type of activating device.

Controlled documents should be reviewed at least once every 2 to 5 years depending on the associated risk. Emergency procedures may need to be reviewed more frequently (e.g., 1 year).

References

Calibration Subject Area

Integrated Safety Management System Program Description

Training and Qualifications Subject Area

Work Planning and Control for Experiments and Operations Subject Area

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Subject Area: ***Internal Controlled Documents***

2. Revising Existing Controlled Documents

Effective Date: **May 2002**

Point of Contact: Quality Representative

Applicability

This information applies to staff responsible for revising existing controlled documents.

Required Procedure

Revising Existing Controlled Documents contains three subsections:
2.1 All Proposed Revisions
2.2 Proposed Revisions for Normal Change
2.3 Proposed Revisions for Work-in-progress Change

Documents that need to be revised must be properly reviewed, approved, and distributed.

Existing controlled documents are revised based on one of the following situations:

- when a staff member recommends a revision that does not impact work in progress (normal change). These revisions may be recommended by any staff member who recognizes a need for change or by an individual designated to review a controlled document during a periodic review.
- when a staff member suggests a revision when work is in process (work-in-progress change).

2.1 All Proposed Revisions

For all proposed revisions, staff follow the steps below.

Step 1	Any staff member identifying the need for a revision to a controlled document submits a marked-up copy of the document to the cognizant manager or designee who is responsible for the document.
Step 2	The cognizant manager or designee determines which situation applies to the document and follows the appropriate steps outlined below: 1. the procedure for normal change can be followed, or 2. the procedure for work-in-progress change is followed to avoid an unnecessary interruption of work

2.2 Proposed Revisions

2.2 Proposed Revisions for Normal Change

If the proposed revision is following the procedure for normal change, staff perform the steps below.

Step 1	The cognizant manager or designee reviews and approves the document. Where appropriate, the cognizant manager or designee ensures that the core functions and guiding principles of the Integrated Safety Management System Program Description are addressed. A hazards analysis is conducted in accordance with the screening criteria of Work Planning and Control for Experiments and Operations Subect Area, and appropriate controls are incorporated into the document. **Note:** The cognizant manager or designee may identify other reviewers depending on the document and the department/division or project-specific process for document control. These reviews can be done in parallel or consecutively.
Step 2	If the cognizant manager or designee does not agree with the proposed revision and attempts fail to resolve differences, these differences are taken to successively higher levels of management until they are resolved. When the differences are resolved, the request for change proceeds as indicated below.
Step 3	The cognizant manager or designee has the approved revision made to the document.
Step 4	The cognizant manager or designee completes the steps outlined in the section Distributing Controlled Documents.

2.3 Proposed Revisions for Work-in-progress Change

If the proposed revision is following the procedure for work-in-progress change, staff perform the steps below.

Step 1	The cognizant manager or designee reviews the proposed revision. Where appropriate, the cognizant manager or designee has the document reviewed to ensure that the core functions and guiding principles of the Integrated Safety Management System Program Description are addressed. A hazards analysis is conducted in accordance with the screening criteria of Work Planning and Control for Experiments and Operations Subject Area, and appropriate controls are incorporated into the document. **Note:** The cognizant manager or designee may identify other reviewers depending on the document and the department/division or project-specific process for document control. These reviews can be done in parallel or consecutively.
Step 2	If the cognizant manager or designee agrees with the proposed revision, they do the following: • initial and date all of the marked-up changes • photocopy the marked-up, initialed, and dated document and give it to the staff member who requested the revision with permission to proceed with the work using the marked-up document for a designated period.
Step 3	If the cognizant manager or designee does not agree with the proposed revision, the document

	remains as written.
Step 4	If the change is intended to be permanent, the cognizant manager or designee has the document revised.
Step 5	The cognizant manager or designee completes the steps outlined in the section Distributing Controlled Documents.

Guidelines

Document Review

For ease of review, a proposed revision to a document should be clearly indicated (i.e., a line in the margin or by highlighted text). When several individuals are reviewing the document, some method of tracking should be used. The Document Review Tracking Sheet provides a suggested form.

Change Tracking

As documents are revised, the incorporated changes should be identified, so that users can determine what has changed in the final version of the document.

Training

Personnel should be notified of changed procedures, to ensure users are trained and qualified to perform their assigned tasks and job functions. Additional details regarding training can be found in the Training and Qualifications Subject Area.

References

Integrated Safety Management System Program Description

Training and Qualifications Subject Area

Work Planning and Control for Experiments and Operations Subject Area

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Subject Area: ***Internal Controlled Documents***

3. Distributing Controlled Documents

Effective Date: **May 2002**

Point of Contact: Quality Representative

Applicability

This information applies to staff who distribute controlled documents.

Required Procedure

Distributing Controlled Documents contains two subsections:

Controlled documents can be distributed in one of two ways:

1. using a controlled distribution list that is tracked and updated, or
2. using a department/division or project-specific process (e.g., web-based), that ensures that the latest revision of relevant documents are available in appropriate locations and are used by the appropriate staff.

Note: Since operator aids do not require a master file, this section is not applicable to operator aids.

3.1 Using a Controlled Distribution List

Staff perform the following steps when using a controlled distribution list to distribute controlled documents.

Step 1	Prepare a document distribution list that identifies the staff who will receive the document and any locations where the document is kept for reference (e.g., a library). **Note:** The cognizant manager or designee should consider whether any training is needed before the document is distributed to staff and take any appropriate steps (i.e., inform affected staff and their management, or arrange for training).
Step 2	Distribute controlled documents per the controlled distribution list. All other copies of such documents are considered uncontrolled.
Step 3	The individual responsible for the controlled document removes and replaces any obsolete documents with the current version or otherwise ensures against unintended use of outdated documents.

Step 4	Update the master file to provide the complete revision history of each document, including the effective date of each revision. Maintain superceded documents per the Records Management Subject Area.

3.2 Using Other Methods of Distribution

Staff perform the following steps when using some method other than a distribution list to distribute controlled documents.

Step 1	The individual responsible for the controlled document removes and replaces obsolete documents with the current version or otherwise ensures against unintended use of outdated documents. **Note:** The cognizant manager or designee should determine if any training is needed before the document is distributed to staff and take appropriate steps (i.e., inform affected staff and their management, or arrange for training).
Step 2	Update the master file to provide the complete revision history of each document, including the effective date of each revision. Maintain superceded documents per the Records Management Subject Area.

Guidelines

All controlled documents should contain a control number.

Request evidence of the document's receipt from the recipients. For example, use the Document Transmittal and Acknowledgment Form. Follow up on any delinquent acknowledgments.

Note: Specify the timeline for signing and returning the form.

When documents are web-based, use a disclaimer such as: "The only official copy of this file is the one the online. Before using a printed copy, verify that it is the most current version by checking the document effective date on this website." Also, there should be a signed hard copy of the document.

References

Records Management Subject Area

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Subject Area: ***Internal Controlled Documents***

4. Using Controlled Documents

Effective Date: **May 2002**

Point of Contact: Quality Representative

Applicability

This information applies to staff who use or receive controlled documents.

Required Procedure

Staff members who use the controlled documents perform the steps below.

Step 1	Ensure you are using the most current version of the controlled document. **Note:** Check with the cognizant manager, if necessary, for the current version.
Step 2	Implement the document as written.
Step 3	Stop work if any of the following criteria are met: • The procedure, instructions, plan, or specifications cannot be performed as written. • Continuation would result in negative operational, ES&H, or compliance impacts.
Step 4	If the work is stopped, immediately ensure that the system, component, or operation is placed in a stable and safe condition, if possible.
Step 5	Notify your cognizant manager about the situation. See the Nonconformance and Corrective and Preventive Action Subject Area for information on reporting a possible nonconformance.
Step 6	If you identify a need for a revision to a controlled document, follow the steps in the section Revising Existing Controlled Documents.

References

Nonconformance and Corrective and Preventive Action Subject Area

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The only official copy of this file is the one online in SBMS. Before using a printed copy, verify that it is the most current version by checking the document effective date on the BNL SBMS website.

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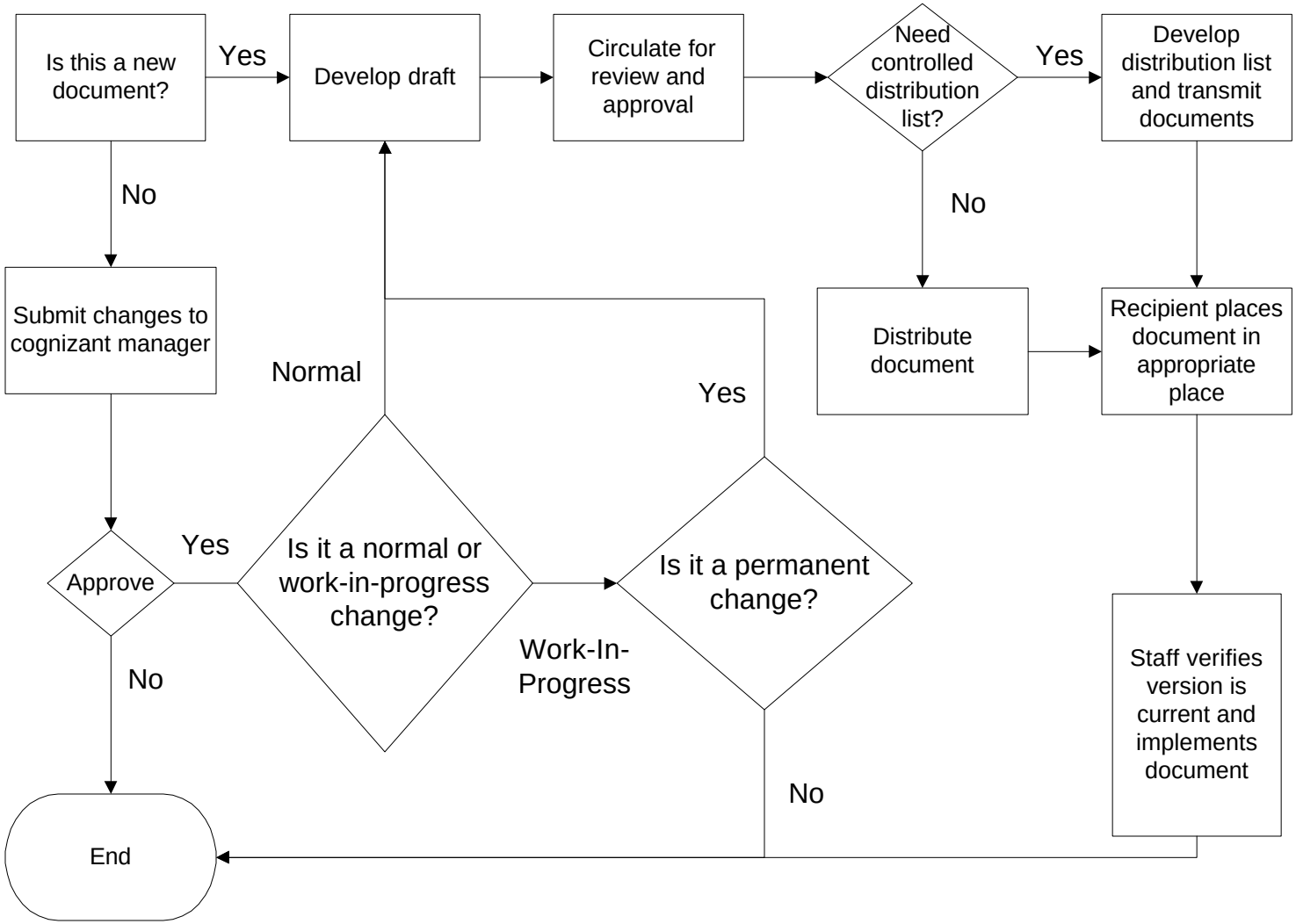
Flowchart of Document Control



Subject Area: ***Internal Controlled Documents***

Guidelines for Developing Procedures

Effective Date: **May 2002**

Point of Contact: Quality Representative

Technical and operating procedures are tools to manage risks and hazards associated with conducting research and operational and maintenance activities. They also are used to ensure that appropriate quality assurance and other client-driven requirements are integrated with work. The following sections provide guidance in developing procedures:

- Process for Developing Procedures
- Format for Writing Procedures
- Guidelines for Writing Procedures

Process for Developing Procedures

Using the process described below will help ensure that

1. stakeholders and users have a voice in developing procedures that affect them,
2. applicable regulatory issues are addressed,
3. hazards and mitigation methods are identified,
4. the procedure is accurate, and
5. stakeholders and users understand how the procedure is to be used.

However, this process is not required and other processes may be used.

Before writing a procedure, consider the need for the following activities:

- Identify and then involve other stakeholders in developing the procedure. Stakeholders may include individuals, such as users of the procedure, affected support functions (i.e., Environment, Safety and Health, and Quality), or organizations responsible for facilities where work will take place (e.g., Facility Safety Review Committee)
- Gather any pertinent background information. Possible options include
    1. interviewing staff who are familiar with similar activities to learn from past experiences or
    2. determining the minimum experience and training levels possessed by the principal users and those required to implement the procedure.
- Identify applicable technical, regulatory, and administrative requirements, such as other subject areas (e.g., Calibration) and manuals; Technical/Operational Safety Requirements, safety analysis reports, specific building safety limits, risks, or facility limits that could be impacted in using the procedure (an Unreviewed Safety Question determination screening may be appropriate); project requirements; vendor and facility information; existing job aids; technical literature (e.g., drawings or engineering specifications); lessons learned, occurrence reports, and root cause analyses; or results of design verification and system tests.
- Review the hazards associated with the activity, such as
    1. physical agents and hazardous environments and materials,
    2. any conditions that would reduce or increase the risks associated with the known hazards, and

potential waste streams. Review the methods determined to control the hazards.

In writing the procedure, the Format for Writing Procedures may be used. Developing a flowchart showing the basic steps, sequence, and hierarchy of the work is also recommended. Guidelines for writing procedures are provided in Guidelines for Writing Procedures.

After writing the procedure, consider the following questions:

- Can the procedure be performed in the sequence it is written?
- Can the user locate and identify all equipment referred to in the procedure?
- Can the user perform the procedure without needing direct assistance or additional information from persons not specified by the procedure?
- Are words, phrases, abbreviations, or acronyms that have special or unique meaning to the procedure defined adequately?
- Is there a need for special controls on collecting data and project recordkeeping?
- Does the procedure address the core functions and guiding principles of the Integrated Safety Management System Program Description?

After completing the procedure, it should be tested to the extent possible (e.g., conduct a walkdown or dry run). Also, it is recommended that at least one technical reviewer verify the accuracy of the procedure, including using the hazard screening guidance in Work Planning and Control for Experiments and Operations Subject Area, if necessary.

Format for Writing Procedures

The format is provided as a Word or PDF file.

1. Content

Show the subject of the guide on each page's heading. The general arrangement or layout of each procedure should include the following major sections in the order listed:

- 1.0 - Purpose (why the document was written)
- 2.0 - Scope (area of application)
- 3.0 - Policy (general description of the plan)
- 4.0 - References (other related information and authority)
- 5.0 - Definitions (main terms where necessary)
- 6.0 - Procedure (detailed narrative).

2. Mechanical Layout

The following are guidelines for the mechanical layout of procedures:

- List definitions alphabetically and underline each term.
- List references numerically.
- Describe procedural steps to be taken and list the individuals responsible for the actions listed.
- Place exhibits, such as diagrams, tables, and figures as close to the descriptive text as possible. Number each exhibit consecutively and include a title.
- Number sections and subsections. If a section contains no information, write "none" or "not applicable" where the text would appear.
- Leave one-inch margins around the page (i.e., top, bottom, left, and right).
- Print on both sides of the page to save paper.

Guidelines for Writing Procedures

The following are guidelines for writing procedures.

1. Procedure Titles, Numbers, and Status

1. Procedure Titles, Numbers, and Status

The title of the procedure should be

- concise, clear, and describe the system, equipment, process, or activity
- applicable to the procedure and activity
- unique (e.g., revision number) to help the user identify the correct procedure.

Number the procedure by using the organization code of the controlling organization (the two-letter designated code), a unique identifier selected by the organization, and the revision status (e.g., Rev. 1 or Rev. A).

2. Instructional Steps

Instructional steps should be concise and precise, using the following guidelines as appropriate:

- When writing several levels of procedures, begin with the more general procedures first and then the more specific procedures. This will force generic information to the highest level, which may then eliminate some repetition in the more specific procedures.
- Identify first-, second-, and third-level headings by a decimal numbering system (e.g., 1.0, 1.1, and 1.1.1). If possible, avoid numbering headings after the third level unless you need to cross-reference the headings, because such numbers can be confusing.
- Make sequential action steps readily distinguishable to the user by numbering the steps. For example, use Step 1, Step 2, Step 3, etc.
- Use bullets for nonsequential information (actions that do not necessarily need to be performed in a particular order or sequence).
- Include only one action in each step.
- Start commands with an action verb, such as the following:

  - Open Valve B-17.

  - Record reading from Strip Chart 1-21 in operations logbook.

- Use conditional action steps when a decision is based on the occurrence of a condition or a combination of conditions (e.g., when the cooling water pump has stabilized, then close the bypass isolation valve).

- Indicate the expected response time when the response to system actions will not be immediate (e.g., "Download the system. This will take approximately 15 minutes.").

- Include specific limits or tolerances for operating parameters values and make them consistent with the readable accuracy of instrumentation. Procedure users should not be required to perform mental arithmetic to determine if a specific parameter is acceptable (e.g., "Operate to 20 to 30 psi," not "Operate to 25 psi±5").

- If individual signoffs are provided for selected critical steps, a signoff should only be used for more than one step.

- Make the administrative control hold points (i.e., where quality, radiological, or other approvals or actions are required before proceeding) clear and concise with measurable objectives. The following are examples of administrative hold points:

  - HOLD POINT: Radiological Control Technician performs a release survey of materials.

  - HOLD POINT: Obtain the Building Manager's approval before continuing.

3. Cautions and Notes

Cautions

Cautions are used to attract attention to information that is essential to safe performance. Notes are used to call attention to supplemental information. A Caution indicates a potentially hazardous situation which, if not avoided, may result in death, injury, or damage to facilities or equipment. The following is an example of a caution statement: Caution: Do not allow temperature to exceed 250°C.

Caution statements should be placed in the procedure as follows:

- If the hazard is present during the entire procedure, place the Caution statement in the Precautions and Limitations section; see Format for Writing Procedures.
- Position the Caution statement so it fits on one page and appears immediately before and on the same page as the actions to which it applies.
- Do not include action steps in Caution statements.
- Write Cautions as concise statements.
- Ensure that Cautions describe the hazardous condition, the consequences of failing to heed the hazard statement, and critical time considerations.
- Include only one topic in each Caution statement.
- Avoid overusing Caution statements.

Notes

Notes call attention to supplemental information. Notes present information that assists the user in making decisions or improving task performance. Guidelines for using notes are given below:

- Place notes after any Caution statements if used at the same point in a procedure. Note: This is an example of a note. The word "Note" is in boldface, followed by a colon, two spaces, and then the text.
- Do not include action steps in Notes.
- Avoid overusing Notes.

4. Documentation of Data or Results

The requested information and steps defined within the procedure should provide sufficient detail that the process described in the procedure can be repeated and yield the same results. The level of detail required will support the ability to analyze anomalies or testing failures, derive corrective actions, and repeat the procedure with a level of confidence to prove the effectiveness of the corrective actions.

The documentation methods should be incorporated as part of the procedure and should specify the following:

- the record document(s) where the data will be recorded (e.g., technical report or project files)
- if the procedure user needs to sign and date the data or results entries
- if the procedure needs to be witnessed by someone other than the procedure user (specify if witness signature and date are required)
- specific information to be recorded in a level of detail sufficient for a reviewer to be able to review the documented record of the data or results and determine the critical elements of who, what, when, where, and how that would provide traceability and substantiate the results or data. The record identifying who, what, when, and how may be provided by including such things as the person(s) conducting or witnessing the procedure, procedure number and date, and the identifying numbers of any critical measurement and testing equipment used. Applications using software should include the name of the software being used and the particular version.

Note: Special attention should be given when "calibrated" measurement and test equipment is called for in the procedure. The documentation method should support notification of possible problems with the calibration results of the equipment after executing the procedure.

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BROOKHAVEN NATIONAL LABORATORY Department/Division/Project	NUMBER	REV.
	DATE	PAGE OF
SUBJECT:	PREPARED BY:	
	APPROVED BY:	

1.0 Purpose

2.0 Scope

3.0 Policy

3.1

4.0 References

4.1

5.0 Definitions

5.1

6.0 Procedure

6.1

6.1.1

6.1.1.1

BROOKHAVEN NATIONAL LABORATORY Department/Division/Project	NUMBER	REV.
	DATE	PAGE OF
SUBJECT:		

DOCUMENT REVIEW
TRACKING SHEET

DOCUMENT TITLE: **REVISION:** **DRAFT:**

RETURN TO:

DATE OF TRANSMITTAL: **RESPONSE DUE DATE:**

REVIEW DISTRIBUTION	REVIEWER'S SIGNATURE & DATE	COMMENTS ATTACHED
		YES/NO
		YES/NO
		YES/NO
		YES/NO
		YES/NO
		YES/NO
		YES/NO
		YES/NO
		YES/NO
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		YES/NO
		YES/NO

IF COMMENTS ARE NOT RECEIVED BY THE REQUESTED RESPONSE DATE, THE REFERENCE DOCUMENT WILL BE CONSIDERED ACCEPTABLE AS IS.

DOCUMENT TRANSMITTAL AND ACKNOWLEDGEMENT

DATE OF TRANSMITTAL:

TO: **FROM:**

DOCUMENT(S) TRANSMITTED:
TITLE **DOCUMENT NO.**

INSTRUCTIONS TO RECIPIENT:

RESPONSE DUE DATE:

ACKNOWLEDGEMENT

I hereby acknowledge receipt of the documents transmitted to me by this form. In the case of revisions, I acknowledge their incorporation into the appropriate documents and have marked/destroyed all superseded documents. I also acknowledge having read the transmitted material as well as verified that the above instruction(s) have been complied with.

COMMENTS:

_____ _____
Signature Date

UPON COMPLETING THE ACKNOWLEDGEMENT SECTION, PLEASE RETURN THIS FORM TO THE SENDER BY THE REQUESTED RESPONSE DUE DATE.

Definitions: Internal Controlled Documents

Effective Date: **May 2002**

Point of Contact: Quality Representative

Term	Definition
controlled documents	Plans, drawings, specifications, standards, procedures, and reports that establish item description and quality requirements; define inspections and tests to determine compliance with technical requirements; or prescribe design, manufacturing operations, processes, installation, construction, or operating and maintenance procedures. Also included are documents that describe performance or results of activities, such as test/inspection reports, or environmental monitoring reports. These documents have been uniquely identified for revision control and have been prepared for distribution. These documents may be in electronic form.
document control	The act of ensuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.
operator aids	Operator aids may come in the following forms: copies of procedures (portion or pages thereof), system drawings, handwritten notes, computer or TV displays, information tags, curves, and graphs. They provide useful information to staff in performing their duties. Operator aids should be used to supplement approved procedures, and not be used in lieu of them.

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Revision History: Internal Controlled Documents

Point of Contact: Quality Program Office

Revision History of this Subject Area

Date	Description	Management System
May 2002	The Introduction section was revised to add the following types of documents that are not covered in the subject area: • Documents prepared by external parties (e.g., equipment operating/maintenance manuals). These external documents can be controlled, when appropriate, by cognizant staff. • A posting or sign, which is a device that is temporarily or permanently affixed as a warning, or to provide information/safety instructions to staff who may be exposed to hazards. They are governed by other requirements or SBMS documents. The section Developing New Controlled Documents, and the section Distributing Controlled Documents were revised to • Require that operator aids only need to be dated and have an approval (initial or signature) when the cognizant manager deems necessary, depending on the risk, importance, and critical nature of the equipment or operation. • Require that EMS or Conduct of Operation-related documents be periodically reviewed. Additional changes were made during the review of the document, removing some requirements for which there were no drivers, and adding guidance on electronic documents. A definition for operator aids was added to the Definitions section.	Quality Management

August 2000	Section 1. Developing New Controlled Documents, Section 2. Revising Existing Controlled Documents, and the exhibit Guidelines for Developing Procedures were revised to include references to • Integrated Safety Management, • Work Planning and Control for Experiments and Operations, • Tracking changes in revised documents, and • Training personnel on use of documents.	Quality Management
July 1999	The "Format for Writing Procedures" section of the Guidelines for Developing Procedures exhibit was provided in a downloadable format.	Quality Management
March 1999	This information was developed by a team using the process for Standards-Based Management development. This Subject Area is a replacement for BNL-QAG-405, "Document Control," BNL Quality Assurance Manual.	Quality Management

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